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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,200	05/29/2001	Shujath M. Ali	DEX-0192	2228

26259 7590 07/30/2003

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/30/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,200

Applicant(s)

ALI ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1, 6 are being examined, wherein claims 1, 6 are examined only to the extent of a method for diagnosing the presence of prostate cancer comprising measuring the mRNA level of a polynucleotide of SEQ ID NO:1.

The following are the remaining rejections.

OBJECTION

Claims 1, 6 remain objected to because part of claims 1, 6 are drawn to non-elected invention, i.e. a method for diagnosing the presence of prostate cancer comprising measuring the protein level of SEQ ID NO:2.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER, NEW REJECTION

Claims 1, 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 6 are drawn to a method for diagnosing the presence of prostate cancer in a patient comprising measuring the levels of SEQ ID NO:1 in "relevant" tissues.

The specification does not disclose nor defines what "relevant" tissues are.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION

Claims 1, 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6 are indefinite for the use of the language "relevant" tissues in claim 1. The term "relevant" in claim 1 is a relative term, which renders the claim indefinite. The term "relevant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Rejection under 35 USC 112, first paragraph of claims 1, 6 pertaining to lack of enablement for a method for diagnosing the presence of prostate cancer comprising measuring the mRNA level of the polynucleotide of SEQ ID NO:1 in "relevant" tissue remains for reasons already of record in paper No.10.

Applicant argues that claim 1 has been amended to include the term "relevant" to indicate which tissues are sampled to determine the presence of prostate cancer.

Applicant's arguments set forth in paper No.12 have been considered but are not deemed to be persuasive for the following reasons:

Rejection remains, because the specification does not disclose how to determine which tissue is relevant to prostate tissue. The term "relevant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

REJECTION UNDER 35 USC 102(e)

Rejection under 35 USC 102(e) of claims 1, 6 pertaining anticipation by US 6,177,244B1 or US 6,287,777 remains for reasons already of record in paper No.10.

It is noted by inadvertent error, claims 1, 6 were rejected under 102(a). It is clear however since the prior art is a patent, it was intended that claims 1, 6 were rejected under 102(e). However, the issue raised remain the same.

Applicant argues that US 6,177,244B1 is not a valid prior art reference, because US 6,177,244B1 was issued on 01/23/2001, whereas the priority date of the instant application is 10/19/98.

Applicant further argues that claim 1 has been amended to state that "a 2-fold increase" is measured in levels of SEQ ID NO:1, wherein the amendment is supported in the specification at page 19, lines 21-27. Applicant asserts that US 6,177,244B1 and US 6,287,777 do not teach what degree of expression is indicative of prostate cancer.

Applicant's arguments set forth in paper No.12 have been considered but are not deemed to be persuasive for the following reasons:

It is noted that although US 6,177,244B1 was issued on 01/23/2001, the filing date of said patent is 02/11/98, which also claims as priority application 08/644,326, filed on 05/10/96. Thus US 6,177,244B1 is a valid prior art reference.

Further, claim 1 has not been amended to state that "a 2-fold increase" is measured in levels of SEQ ID NO:1. Moreover, the specification at page 19, lines 21-27 does not disclose that "a 2-fold increase" is measured in levels of SEQ ID NO:1 in prostate cancer.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

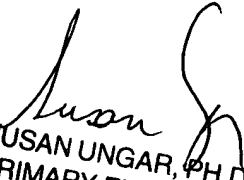
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1642

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.



SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

July 25, 2003